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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,197	11/03/2003	Richard Carleton Gowan	PC17521	3958

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PFIZER INC
10555 SCIENCE CENTER DRIVE
SAN DIEGO, CA 92121

EXAMINER

RAE, CHARLESWORTH E

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/700,197

Applicant(s)

GOWAN ET AL.

Examiner

Charleswort Rae

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-25 are currently pending and are the subject of this Office action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to an anticancer combination comprising a mitotic inhibitor and a MEK inhibitor, classified in class 514, subclasses 248, 449, 478, and 510. If this Group is elected, then the below summarized Species Election is also required.
- II. Claims 11-25, drawn to a method for treating cancer in a patient comprising administering to a patient in need of treatment a mitotic inhibitor and a MEK inhibitor, classified in class 514, subclasses 248, 449, 478, and 510. If this Group is elected, then the below summarized Species Election is also required.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, invention 1 may be practiced by another materially different process of using the product. For example, invention I may be practiced by a materially different method for treating atherosclerosis.

Because inventions I-II are independent or distinct for the reasons given above coupled with the fact that a search is required for each group, restriction for examination purposes is proper. While inventions I-II can be identically classified under U.S. Patent Classification guidelines, to search them together would present an undue search burden on the Examiner due to the extensive databases of patent and non-patent literature that would have to be searched in view of the divergent subject matter encompassed by these different groups. Thus, Groups I-II have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Election of Species regarding Groups I-II

This application contains claims directed to more than one species of the generic inventions that would require an unduly extensive and burdensome search by the examiner if all the claimed species were examined together.

The generic inventions encompass multiple species of mitotic inhibitors and MEK inhibitors. For example, the generic inventions encompass the following mitotic inhibitors:

a) paclitaxel, b) docetaxel, c) vincristine, d) vinblastine, e) vinorelbine, and f) vinflunine (i.e. claim 3).

Each of the above species represents a different chemical compound. The species are independent or distinct because the agents are different chemical compounds and have acquired a different status in the art. In view of the undue search burden that will be created by the multiplicity of chemical compounds encompassed by these claims,

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applicant is required to elect one specie of mitotic inhibitors for examination purposes e.g. paclitaxel.

As stated above, the generic inventions also encompass multiple species of MEK inhibitors, including the following:

i) non-selective MEK inhibitors, ii) selective MEK1 inhibitors, and iii) selective MEK2 inhibitors.

The species are independent or distinct because each of the above species exhibits a different pharmacologic effect. In view of the undue search burden that will be created by the multiplicity of chemical compounds encompassed by these claims, applicant is required to elect one single specific specie of MEK inhibitors for examination purposes.

For example, if applicant elects i) non-selective MEK inhibitors, applicant is further required to elect a single non-selective MEK inhibitor for examination purposes.

For example, if applicant elects ii) selective MEK1 inhibitors, applicant is further required to elect a single specific selective MEK1 inhibitor for examination purposes.

For example, if applicant elects iii) selective MEK2 inhibitors, then applicant is further required to elect a single specific MEK2 inhibitor for examination purposes e.g.

If applicant elects a phenyl amine MEK inhibitor compound of Formula I, then applicant is further required to elect is single specific compound wherein all variables and optional groups are specifically defined with respect to R1, R2, R3, R4, R5, Br/I, m, n, R9, R10, R11, Z, R6, and R7.

Similarly, if applicant elects a phenyl amine MEK inhibitor compound of Formula II, then applicant is further required to elect a single specific compound wherein all

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variables and optional groups are specifically defined with respect to R1a, R2a, R3a, R4a, R5a, R6a, R7a, Br/I, m, n, R9a, R10a, and R11a.

In addition, applicant is further required to elect a single combination wherein each constituent of the combination is specifically defined e.g. paclitaxel and 2-(2-amino-3-methoxyphenyl)-4-oxo-4H-[1]benzopyran; or vincristine and 2-(2-chloro-4-iodophenylamino)-N-cyclopropylmethoxy-3,4-difluorobenzamide.

Additional Election of Species regarding Groups I-II

The generic inventions encompass multiple species of cancers, including leukemia, lymphoma, breast cancer, brain cancer, sarcoma, and multiple myeloma.

The species are independent or distinct because each specie represents a different morphologically distinct tumor types that have acquired a different status in the art. In view of the undue search burden that will be created by the multiplicity of chemical compounds encompassed by these claims, applicant is required to elect one cancer specie as appropriate for examination purposes.

The above species are distinct as they represent different chemical and morphological entities. The divergent subject matter, coupled with the fact that the species have acquired a different status in the art, creates a search burden on the examiner. In view of the undue search burden that will be created by the multiplicity of mitotic inhibitors, MEK inhibitors, and cancers the restriction requirement is deemed proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is

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finally held to be allowable. Currently, claims 1, and 11 are considered generic to the above listed species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention; the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

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All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

17 December 2006
CER

Ardin H. Marschel 12/30/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER